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| 09/890,752      | 11/30/2001  | Eberhard Hildt       | VOS-013-107070120   | 7711             |

7590

06/17/2003

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/890,752

Applicant(s)

HILDT ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19- 51 is/are pending in the application.
- 4a) Of the above claim(s) 34- 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19- 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 30 November 2001 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that that all are related or alternatively they relate to one inventive concept. This is not found persuasive because under the Rules for 371 applications Applicant is entitled to the first product, the virus particle, first method of making and first method of using (none claimed). The second method of making and the different products are different inventions. However, should the product be found allowable rejoinder may be possible. Applicant is advised that a rejoinder of claims is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.

To facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action

Claims 34- 51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19- 33 are under consideration in this action.

### ***Preliminary Amendment***

The Office requests clarification on the cancellation of claims as directed by the Preliminary Amendment. The communication directed the Office to cancel claims 1- 17 and stated that "This list represents all of the pending claims" which were numbered 18- 50 but renumbered by the Office because a claim 18 was still pending in the application as filed. Claim 18 was treated as cancelled in the Restriction Requirement. Applicant is requested to cancel 18 the claim if that was the action intended.

### ***Drawings***

The proposed drawing corrections, filed on 23 March 2002 have been accepted. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance. The corrected drawings are still subject to review by the Draftsman.

***Information Disclosure Statement***

A signed and initialed copy of IDS paper #4 is enclosed.

***Claim Objections***

Claims 30 and 32 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 29 and 31, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The terms "has" and "comprises" are both treated as open language by the Office, thus the claims have no difference in scope or meaning.

Claim 23 is objected to because the abbreviation "LHBs" should be spelled out the first time it appears in the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19- 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what "cell permeability-mediating

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peptide" is or how this differs from normal viral proteins that allow for attachment and entry of virus. The term is defined on page 2 paragraph 7 as " any peptides capable of mediating a cell permeability of substances, in particular proteins." It is not clear what the metes and bounds of the meaning of this term or what the functional limitations are. Furthermore, it is not clear if this term refers to making the cell membrane itself permeable (as in the membrane is more porous to any matter inside and outside the cell or if it forms a pore such as an ion channel. In claim 1 (b) it not clear if the meaning of "nucleic acid present in the protein envelope" means contained within the particle or if the nucleic acid sequences are part of the envelope.

Claim 20 is not clear as to the metes and bounds of "derived", and how much changed from the original protein. The "derived" appears to be a portion of a viral envelope protein or is it mutated or altered as well?

Claim 33 is not clear because in part (a) it not clear what is meant by "cells containing a hepatitis B virus genome, wherein the cells do not express LHBs", because a cell containing an HBV genome would produce LHBs or does the genome not produce its own. Also, there is no indication that the step (a) that particles are made to be isolated in (b).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19- 25, 27- 29, 31, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The term "cell permeability-mediating peptide" is not defined in such a way to allow one of ordinary skill in the art to know what the structural basis is. The term is defined by function only. The specification provides one example (SEQ ID No:20). There is no indicated structure described that can be used to determine all possible peptides that have this function.

Due to the vagueness of the term and lack of clear definition as discussed above, it is concluded that the Applicant had only the one sequence in their possession at the time of the invention. Therefore, only SEQ ID NO: 20, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 20, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg (WO 97/24453).

Rosenberg discloses a particle that comprises a fusion envelope protein (a chimeric viral surface protein constructed to include a portion of viral surface protein which mediates cell permeability by allowing binding and internalization of the particle and a heterologous cell specific binding site) and within the fusion envelope protein is contained a structural gene (abstract, page 14, and Examples 1- 7).

Claims 19- 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schodel.

Schodel discloses a particle that comprises a protein envelope with a fusion protein comprising a virus protein, a permeability mediating peptide and a heterologous cell specific binding site (specific T-cell recognition) and contains within a structural gene (see entire document).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers




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for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill  
Patent Examiner  
June 15, 2003



JAMES HOUSEL 6/16/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600